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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/643,407

Applicant(s)

PEER ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 14, 16-21, 23 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 22, 24-29, and 31-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449)

3 Sheets

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicants' election with traverse of the first specie (Group I, First Embodiment), second specie (Group III, detecting or genotyping somatic mutations), and third specie (Group II, polynucleotide sequence) in Paper No. 8, filed 11/23/01, is acknowledged. Applicants' request that all species be examined is not found persuasive since applicant did not distinctly and specifically point out the supposed errors in the specie election requirement. It has been shown in Paper No. 7 that the specie requirements are directed to patentably distinct embodiments (algorithms), differing methods of detection, and different chemical types. The requirement is still deemed proper and is therefore made FINAL. Therefore, claims 14, 16-21, 23 and 30 are withdrawn from consideration as not directed to the elected groups.

Claims herein under examination are claims 1-13, 15, 22, 24-29, and 31-32.

OBJECTION TO DISCLOSURE

The disclosure (specification, page 2, line 14) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01.

Claims Rejected Under 35 U.S.C. 112 § 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

LACK OF ENABLEMENT

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claim 6 (line 3) the step/equation “ $L^c(\hat{T}) = \prod_{\bar{x} \in A} P_{\hat{T}(\bar{x})}(\bar{x})$ ” is not enabled and thus fails to provide guidance to practice, particularly the variable A. In order to determine the score of a candidate nucleotide sequence the evaluation of the above equation as stated is required. The lack of the equation parameter A would not provide one skilled in the art sufficient guidance to perform and thus is unpredictable and therefore would require undue experimentation.

Claim 25 (line 3) the step/equation “ $L^c(\hat{T}) = \prod_{\bar{x} \in A} P_{\hat{T}(\bar{x})}(\bar{x})$ ” is not enabled and thus fails to provide guidance to practice, particularly the variable A. In order to determine the

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score of a candidate nucleotide sequence the evaluation of the above equation as stated is required. The lack of the equation would not provide one skilled in the art sufficient guidance to perform and thus is unpredictable and therefore would require undue experimentation.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15, 22, 24-29, and 31-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and claims dependent therefrom are vague and indefinite due to the inconsistency between the preamble and the method steps. In line 1 of claim 1 the intent of the method is apparently to obtain "a candidate nucleotide sequence", but confusingly, the last 2 lines of claim 1 select "one or more candidate nucleotide sequences." The "or more" phrase is different from the intent of the method as set forth in said line 1 and makes the claim vague and indefinite as to how many candidates are required for the claim practice. Is there one candidate that meets the preamble which apparently is not defined in the claim?

Claims 1 (all claims dependent therefrom), 31, and 32 are vague and indefinite in that part (b) of claims 1, 31, and 32 assigns a score based on a probabilistic spectrum and one reference sequence but confusingly without indicating what the scoring algorithm is which calculates spectrum + sequence. Since the specification is believed to specify scoring

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algorithms, the claim is not commensurate in scope with the specification because of the unspecific claim versus the non-commensurate specification.

Claim 6, 7, 9, and 25 the phrase "score is based upon" is set forth wherein a mathematical formula then follows. These claims are vague and indefinite in that they are not commensurate in scope with the specification wherein the score is specifically calculated via a formula which specifically incorporates said mathematical formula rather than some undefined "based upon" practice. See, for example, claim 10 which, in contrast, is not vague and indefinite in this regard because a score is specifically calculated via clear and concise formulations rather than an undefined "based upon" relationship.

Claim 12 (line 4) the "predetermined constant" implies that the constant is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what constant is chosen: 1. Limited to requiring some specified constant or 2. Inclusive of random arbitrary constant. The implied criterion is critical in applying it to the "predetermined constant", and therefore it is unclear.

Claim 24 (lines 2-3) the "predetermined value" implies that the value is chosen by some kind of criteria. Applicant can resolve this issue by particularly pointing out what value is chosen: 1. Limited to requiring some specified value or 2. Inclusive of random arbitrary value. The implied criterion is critical in applying it to the "predetermined value", and therefore it is unclear.

LACK OF ANTECEDENT BASIS

Claim 12 recites the limitation "equations (14) and (15)" on line 9. There is a lack of antecedent basis for this limitation in the claim as to the referred equation.

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Claim 12, line 6, recites the limitation "computing $S''[\bar{y}, j]$ according to claim 10". There is a lack of antecedent basis for this limitation in claim 10.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 31, and 32 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Sharaf (U.S. Patent 5, 873, 052).

Sharaf teaches an alignment-based similarity scoring method for quantifying differences between closely related polymorphic biopolymer sequences, said method allows for the identification of sequences (Abstract). The inventor assigns a probability score to determine sequence matching to the complement of the basis set/k-mers to obtain a probabilistic spectrum [0,1] (Column 2, lines 45-67, Column 3, lines 1-63, and Column 6, lines 21-60). The steps described are performed in a program storage device including computer readable medium (Column 9, lines 7-14). The hybridization signals are obtained from a DNA Sequencer (Column 9, Example 1). Sharaf illustrates a method for scoring related sequences wherein the test sequence is selected (maximum score of 100%) from the set sequences (Column 10, Example 2, lines 34-42). Thus, Sharaf clearly anticipates the claimed invention.

MINOR INFORMALITIES

Claim 11, part (a), is objected to because of the following informalities: missing closing bracket. Appropriate correction is required.

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Claim 12 is objected to because of the following informalities: the term "settting" is misspelled, part (a). Appropriate correction is required.

Appropriate Correction Is Required.

No Claim Is Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

Jan 24, 2002
CSM

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER